The opinion in support of the decision being entered today was ***not*** written for publication and is ***not*** binding precedent of the Board

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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FEB 12 2002

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte M. RIGDON LENTZ

Appeal No. 2001-2168
Application No. 09/083,307

HEARD: December 12, 2001

Before MCCANDLISH, Senior Administrative Patent Judge, FRANKFORT and BAHR, Administrative Patent Judges.

MCCANDLISH, Senior Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1 through 23. No other claims are pending in the application.

Appellant's invention relates to a method (claims 1-8) for inducing an immune response against transformed, infected or diseased tissue, a system (claims 9, 16 and 18-22) for inducing an immune response against transformed, infected or diseased tissue, and a kit (claims 10-15, 17 and 23) for the treatment of a patient to induce an immune

response against transformed, infected or diseased tissue. Appellant's invention is useful in the treatment of cancer.

According to appellant's invention, the patient's blood is pumped through a filter having a cutoff of 120,000 daltons[1] to remove those blood components having molecular weights equal to or less than the filter cutoff and comprised of immunosuppressive components. The removal of the immunosuppressive components by the filter is said to improve the patient's immune response to the disease or infection being treated.

A copy of the appealed claims is appended to appellant's brief.

The following references are relied upon by the examiner as evidence of obviousness in support of the rejections under 35 U.S.C. § 103:

Lentz	4,708,713	Nov. 24, 1987
Okarma et al. (Okarma)	5,523,096	Jun. 04, 1996
Wolpe	5,861,483	Jan. 19, 1999

[1] The manner in which the filter is disclosed and claimed in appellant's application presupposes a predetermined relationship between the size of the components in the blood and the molecular weight of those components (e.g., the smaller the size, the smaller the molecular weight). We understood that it is customary in the art to define the size of membrane filters or ultra filters, as they are also called, in terms of the molecular weight of the blood components passed by the filter.

Chen et al., "Soluble TNF-alpha receptors are constitutively shed and downregulate adhesion molecule expression in malignant gliomas." Journal of Neuropathology and Experimental Neurology, vol. 56, no. 5 (May 1997) pp.541-550

The appealed claims stand rejected under § 103 as follows:

1. Claims 1-4, 8, 9, 16, 18-20 and 22 as unpatentable over Lentz;

2. Claim 21 as unpatentable over Lentz in view of Okarma;

3. Claim 7 as unpatentable over Lentz in view of Chen; and

4. Claims 5, 6, 10-15, 17 and 23 as unpatentable over Lentz in view of Wolpe.

Reference is made to the examiner's answer for details of the foregoing rejections.

With regard to the first rejection listed above (i.e., the rejection based on Lentz alone), we note that claims 1-4, 9 and 18-20 have been grouped together by appellant for determining the issue of patentability (see page 4 of the main brief). This group of claims has been identified as group 1[2] on page 11 of the main brief. Under these circumstances, we are authorized under 37 CFR

[2] On page 4 of the main brief, roman numerals are used to

§ 1.192(c)(7), as amended effective April 21, 1995, to select a single claim from the group in question, namely group 1, and to decide the appeal of the claims in group 1 on the basis of the patentability of that representative claim alone. Accordingly, we will select claim 9 as being representative of group 1, with the result that the remaining claims in that group, namely claims 1-4 and 18-20, shall stand or fall with claim 9. See also In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Wood, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978).

Claim 9 is directed to the system of inducing an immune response and reads as follows:

> A system for inducing an immune response against transformed, infected or diseased tissue comprising a device for removing only components present in the blood having a molecular weight of 120,000 daltons or less, having inlet and outlet means for connection to a pump and tubing to recirculate the blood of a patient through the device.

As noted from the foregoing copy of claim 9, the structure recited in claim 9 comprises the filter device for removing only components having a weight of 120,000

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identify the different groups of claims, whereas on page 11 of the main brief decimal numerals are used for this purpose. For consistency, we will use the decimal numerals mentioned on page 11 of the brief for identifying the different groups of claims.

daltons or less.[3] Claim 9 additionally recites that the filter device has an inlet for connection to a pump (which pumps the blood from the patient to the filter device) and an outlet for connection to tubing to recirculate retentate or treated blood to the patient.

The Lentz patent discloses a blood filtering system that is used for the same purpose as appellant's system. In fact, appellant is the patentee named in the cited Lentz patent. The blood filtering system disclosed in the Lentz patent is basically the same as the system disclosed and claimed in appellant's instant application. Like appellant's system, the system disclosed in the Lentz patent mainly comprises a membrane filter (17), a pump (16) for pumping blood from the patient to the inlet of the filter, and tubing (23) connected to an outlet of the filter to recirculate treated blood to the patient. Like appellant's blood filter, the purpose of the filter in the Lentz patent is to remove immunosuppressive components from the recirculated blood to improve the response of the patient's immune system to infection or disease.

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[3] Consistent with appellant's specification, this claim limitation is interpreted to mean that the filter device is effective to remove all blood components in the range from zero daltons to and including 120,000 daltons.

In support of patentability, appellant argues that "there is no disclosure [in the Lentz patent] of using a filter with a molecular weight cutoff of 120,000 daltons . . ." (main brief, page 7). As far as claim 9 is concerned, no other limitations are argued as differences over the Lentz patent.

Admittedly, Lentz does not expressly set forth in haec verba that any of the membrane filters mentioned in his patent has a molecular weight cutoff of 120,000 daltons. However, the claim limitation is met or anticipated if any of the filters described in the Lentz patent inherently possesses a cutoff of 120,000 daltons given a set of appropriate operating conditions.[4] See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), and In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971).

In the present case, appellant's specification states on page 4 that a membrane filter having a pore size of 0.03 microns and a thickness of less than 25 microns and preferably less than 10 microns will provide the desired cutoff of 120,000 daltons. The Lentz patent discloses a

[4] Claim 9 does not specify any operating conditions.

filter membrane pore size range of 0.03-0.07 microns (column 4, lines 63-64) and a filter membrane thickness of less than 25 microns and preferably less than 10 microns (column 5, lines 12-13). This prior art disclosure constitutes description of a membrane filter having a pore size corresponding to appellant's pore size, namely 0.03 microns, and a thickness corresponding to appellant's thickness, namely less than 25 microns and preferably less than 10 microns.

Thus, there is sufficient basis in fact and/or technical reasoning to reasonably support the determination that the inherent characteristic of a 120,000 dalton cutoff for Lentz's filter necessarily flows from Lentz's teaching of the filter pore size and the filter thickness set forth above. See Best 562 F.2d at 1255, 195 USPQ at 433, Ludtke 441 F.2d at 664, 169 USPQ at 566, and Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int. 1990). The burden therefore shifts to appellant to prove that the subject matter shown to be prior art does not possess the filter cutoff characteristic of appellant's claimed invention. See In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1985) and Best 562 F.2d at 1255, 195 USPQ

at 433. No evidence has been introduced to satisfy this burden. Compare Ludtke 441 F.2d at 664, 169 USPQ at 566.

In the present case, therefore, the subject matter of claim 9 is anticipated by the Lentz patent because each and every limitation in claim 9 is disclosed, either expressly or inherently, in the Lentz patent. See Schreiber, 128 F.3d at 1477, 44 USPQ2d at 1431. With regard to appellant's examples on pages 12-14 of the specification and appellant's argument on page 7 of the main brief, evidence of nonobviousness or teaching away in the art is not relevant where, as here, the rejection is based on lack of novelty. See In re Malagari, 499 F.2d 1297, 1301, 182 USPQ 549, 553 (CCPA 1974). Furthermore, the rejection of claim 9 under § 103 is nonetheless proper since anticipation is the epitome of obviousness. See In re May, 574 F.2d 1082, 1089, 197 USPQ 601, 607 (CCPA 1978).

For the foregoing reasons, we will sustain the examiner's § 103 rejection of claim 9. We will also sustain the examiner's § 103 rejection of claims 1-4 and 18-20 since, as noted supra, these claims were argued as a group with claim 9 and therefore fall with claim 9. In addition, we will also sustain the examiner's § 103 rejection of claims 8 and 22 since appellant has not

challenged the rejection of these claims with any reasonable specificity, thereby allowing these claims to fall with their respective parent claims. See In re Nielson, 816 F.2d 1567, 1572, 2 USPQ 1525, 1528 (Fed. Cir. 1987). In fact, claim 22 is not mentioned in appellant's grouping of claims (see pages 4-5 of the main brief) or in the argument section of appellant's main brief or in appellant's reply brief. Claim 8 is mentioned only indirectly by referring to the group (i.e., group 4) containing claim 8 in part VI of the argument section of the main brief (see page 11), which pertains to the grouping of the appealed claims. Merely asserting that the specific groups require "a separate analysis" as appellant has done on page 11 of the main brief does not establish why claim 8 would be patentable over the prior art separately of claim 9. Moreover, such an assertion does not challenge the rejection of claim 8 with the reasonable specificity required by Nielson.

According to the section in appellant's main brief concerning the grouping of claims (see page 4), claims 5, 6, 10-17 and 23 have been grouped together by appellant for determining the issue of patentability. This group of

claims is identified on pages 4 and 11 of the main brief as group 2. We are therefore authorized under 37 CFR § 1.192(c)(7), as amended effective April 21, 1995, to select a single claim from group 2, and to decide the appeal of the claims in group 2 on the basis of the patentability of that representative claim alone. Accordingly, we will select claim 16 as being representative of group 2, with the result that the remaining claims in that group, namely claims 5, 6, 10-15, 17 and 23, shall stand or fall with claim 16. See also In re Young, 927 F.2d at 590, 18 USPQ2d at 1091 and In re Wood, 582 F.2d at 642, 199 USPQ at 140.

Claim 16 depends from claim 9 and recites that the system "includes means for administering radiation to the tissue." In support of the § 103 rejection of claim 16, the examiner states on page 5 of the answer that radiation treatment of infected or diseased tissue is a well-known practice in the field of appellant's invention. The examiner also states on page 5 of the answer that it also is well known in the prior art to combine radiation treatment with other methods of cancer treatment. Appellant has not challenged these findings.

The well-known benefits of using radiation to treat cancer together with the common knowledge of utilizing radiation with other types of treatment would have provided ample motivation for one of ordinary skill in the art to supplement Lentz' blood-filtering treatment of cancer with radiation to kill residual cancer cells not successfully inhibited by Lentz' treatment.

Nowhere in appellant's briefs do we find any argument expressly disputing the examiner's position that it would have been obvious to supplement Lentz' treatment with a radiation treatment. Indeed, the only argument expressly referring to the group of claims containing claim 16 is found on page 11 of appellant's main brief where it is merely stated that the patentability of groups 1-4 of the appealed claims "require [sic] a separate analysis." That assertion does not amount to an argument that claim 16 is patentable over the prior art separately of claim 9.

For the foregoing reasons we are satisfied that the examiner has established a prima facie case of obviousness with respect to the subject matter claim 16.

According to the section in appellant's main brief concerning the grouping of claims (see page 4), claims 7 and 21 have been grouped together by appellant for

determining the issue of patentability. This group of claims is identified on pages 4 and 11 of the main brief as group 3. We are therefore authorized under 37 CFR § 1.192(c)(7), as amended effective April 21, 1995, to select a single claim from group 3, and to decide the appeal of the claims in group 3 on basis of the patentability of that representative claim alone. Accordingly, we will select claim 7 as being representative of group 3, with the result that the remaining claim in that group, namely claim 21, shall stand or fall with claim 7. See also In re Young, 927 F.2d at 590, 18 USPQ2d at 1091 and In re Wood, 582 F.2d at 642, 199 USPQ at 140.

Claim 7 calls for the removal of soluble TNF receptor 1 and receptor 2 molecules. In support of the § 103 rejection of this claim, the examiner has made the finding on pages 6-7 of the answer that being soluble in the patient's blood, the TNF receptor 1 and receptor 2 molecules will be removed along with the other blood components, presumably by Lentz's membrane blood filter. In any case, the examiner has made the additional finding that Chen teaches that TNF receptor 1 and receptor 2 molecules help to evade the immune response against a tumor as set forth on page 549 of the Chen publication. The

therefore concludes that it would have been obvious to remove the TNF receptor 1 and receptor 2 molecules in view of the known effect of these receptors on the patient's immune response.

Appellant does not challenge the examiner's position that it would have been obvious to remove the TNF receptor 1 and receptor 2 molecules for the reasons discussed above and on page 7 of the answer. Appellant also concedes that Chen teaches the art that the TNF receptors suppress the patient's ability to fight cancer (see page 9 of the main brief). However, appellant is understood to argue in substance (see page 9 of the main brief) that Lentz lacks a teaching of a filter having a cutoff of 120,000 daltons, with the result that the examiner's proposed combination of Lentz and Chen "is not the same as what appellant is claiming" (main brief, page 9). This argument does not challenge the examiner's position on obviousness as discussed supra. We are therefore satisfied that the examiner has established a prima facie case of obviousness with respect to the subject matter claim 7 in light of the reasons discussed above as well as our findings regarding the Lentz patent.

In evaluating appellant's evidence of nonobviousness (namely the comparative examples set forth on pages 12-14 of appellant's specification), we are mindful of the necessity of reweighing the entire merits of the matter and hence considering all of the evidence of record anew. In re Piasecki, 745 F.2d 1468, 1474, 223 USPQ 785, 788 (Fed. Cir. 1984).

With regard to comparative tests such as appellant's examples as set forth on pages 12-14 of the specification, it is necessary to compare appellant's claimed invention with the closest prior art in order to rebut a prima facie case obviousness. See In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) and In re Merchant, 575 F.2d 865, 869, 197 USPQ 785, 788 (CCPA 1978).

In the present case, the examples set forth on pages 12-14 of appellant's specification compare appellant's invention[5] with conventional treatments such as radiation therapy and chemotherapy (see, for instance, example 2 on page 13 of the specification). However, on the record before us, the closest prior art is the blood filtration treatment disclosed in the applied Lentz patent, not such

[5] The examples set forth on pages 12-14 of appellant's specification do not specify the filter cutoff. However, we presume that it is 120,000 daltons.

conventional treatments as radiation and chemotherapy. The examples disclosed in appellant's specification do not compare the results produced by appellant's claimed invention with results achieved by treatment with Lentz' blood filtration system. For this reason alone, appellant's evidence of nonobviousness has little probative weight.

Furthermore, evidence of nonobviousness is not entitled to probative weight where the feature or characteristic responsible for the asserted success is found in the prior art and thus is not a novel characteristic of the claimed invention. See Atiebolaget Karlstads Mekaniska Wedsrdstad v. United States International Trade Commission, 705 F.2d 1565, 1573, 217 USPQ 865, 874 (Fed. Cir. 1983). See also In re Heldt, 433 F.2d 808, 811, 167 USPQ 676, 679 (CCPA 1970) (the asserted success must be the direct result of the unique characteristics of the presently claimed invention). According to our findings as discussed supra, the Lentz patent inherently discloses a blood filter having a cutoff of 120,000 daltons for a set of appropriate operating conditions. Therefore, a blood filter as claimed is not a unique characteristic of appellant's invention.

There are also additional factors that detract from the probative weight to be accorded to appellant's comparative test results. In the first place, appellant has proffered no evidence of the success rate, particularly the clinical success rate, of appellant's claimed invention. The record before us even lacks evidence of the total number of patients who received appellant's treatment. In addition, if appellant's claimed treatment is as effective as appellant claims it to be, one would expect that appellant's claimed invention would have received favorable reports by independent, unbiased observers in medical journals or other publications. The lack of such reports further detracts from the weight to be accorded to appellant's comparative test results.

In his reply brief, appellant cites In re Soni, 54 F.3d 746, 749, 34 USPQ2d 1684, (Fed. Cir. 1995). However, In re Soni simply makes it clear that evidence of unexpected results must be considered in evaluating the obviousness of a claimed invention. See Richardson-Vicks Inc. v. The Upjohn Co., 122 F.3d 1476, 1483, 44 USPQ2d 1181, 1186 (Fed. Cir. 1997). In the present case, appellant's comparative examples have been fully considered.

However, after reviewing all of the evidence before us, we are satisfied that when all the evidence is considered, including the totality of the evidence of nonobviousness, the evidence of nonobviousness is insufficient to overcome the evidence of obviousness as in Ryko Mfg. Co. v. Nu-Star, Inc., 450 F.2d 714, 719, 21 USPQ2d 1053, 1058 (Fed. Cir. 1991). We will therefore sustain the § 103 rejections of claims 7 and 16. We will also sustain the § 103 rejection of claim 21 because claims 7 and 21 have been argued as a group as noted supra. In addition, we will sustain the § 103 rejection of claims 5, 6, 10-15, 17 and 23 because claims 5, 6, 10-17 and 23 also have been argued as a group as noted supra.

Under the provisions of 37 CFR § 1.196(b), the following new grounds of rejection are entered against claims 10 through 15, 17, 21 and 23:

1. Claims 10-15, 17, 21 and 23 are rejected under 35 U.S.C. § 112 ¶ 2 as being indefinite and hence as failing to particularly point out and distinctly claim the subject matter which appellant regards as his invention.

2. Claim 21 is rejected under the first paragraph of 35 U.S.C. § 112 as being based on a specification which, as

filed, does not satisfy the description requirement in that paragraph.

3. Claims 10-15, 17 and 23 are rejected under the first paragraph of 35 U.S.C. § 112 as being based on a specification which fails to provide an enabling disclosure.

(1.) → With regard to our new rejection of the appealed claims under the second paragraph of § 112, it is established patent law that the claims must define the metes and bounds of the invention with a reasonable degree of precision. In re Venezia, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976). Furthermore, it is well settled that a claim in an application must accurately define the applicant's invention. In re Knowlton, 481 F.2d 1357, 1366, 178 USPQ 486, 492 (CCPA 1973).

Our difficulty with the language in claim 17 centers on the recitation that the agent in the kit may be radiation per se. The term "radiation" is defined in Webster's Third New International Dictionary (G. & C. Merriam Company, 1971) as "radiant energy in the form of rays." It is not clear how "rays" (which lack molecular substance) can be physically retained or incorporated into a kit for later use in the treatment of a patient. Being

directly or indirectly dependent from claim 17, claims 10-15 and 23 are subject to the same criticism as claim 17.

Claim 21 depends from claim 9 and recites that the device of claim 9 is an "absorbant [sic, absorbent?] column." Claim 9 recites that the device functions to remove only those blood components having "a molecular weight of 120,000 daltons or less," that is a device having a single cutoff of 120,000 daltons (see footnote 3 supra). It is not clear how an absorbent column (which resolves mixtures) can be defined as having such a single cutoff.

For the foregoing reasons, claims 10-15, 17, 21 and 23 do not define the metes and bounds of the invention with the degree of precision required in Venezia.

With regard to the new ground of rejection of claim 21 under the first paragraph of § 112, there is no descriptive support in the original specification, including the original claims, or the original drawings that the device of claim 9 is an absorbent column. As a result, the disclosure in appellant's application as originally filed does not reasonably convey to the artisan that appellant had possession at that time of the subject matter now recited in claim 21. Thus, with regard to the subject matter of claim 21, the disclosure as originally filed does

not satisfy the description requirement in the first paragraph of § 112. See In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

(3) With regard to the new ground of rejection of claims 10-15, 17 and 23 under the first paragraph of § 112, the dispositive issue with regard to the enablement requirement is whether an applicant's disclosure, considering the level of ordinary skill in the art as of the date of the applicant's application, would have enabled a person of such skill to make and use the claimed invention without undue experimentation. In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982). This test is not met for enabling one of ordinary skill in the art to incorporate radiation per se (i.e., radiant energy in the form of rays) into a kit for later use in the treatment of a patient.

In summary, the examiner's decision to reject claims 1-4, 8, 9, 16, 18-20 and 22 as unpatentable over Lentz is affirmed, the examiner's decision to reject claim 21 as unpatentable over Lentz in view of Okarma is affirmed, the examiner's decision to reject claim 7 as unpatentable over Lentz in view of Chen is affirmed, the examiner's decision to reject claims 5, 6, 10-15, 17 and 23 as unpatentable

over Lentz in view of Wolpe is affirmed, and new grounds of rejection of claims have been entered against claims 10 through 15, 17, 21 and 23 under 37 CFR § 1.196(b). Since our rationale supporting the examiner's § 103 rejections differs from the examiner's position, we herewith designate our affirmance of all of the examiner's rejections as new grounds of rejection under 37 CFR § 1.196(b).

This decision contains new grounds of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides, "[a] new grounds of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner . . . .

> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record . . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED/37 CFR § 1.196(b)

HARRISON E. MCCANDLISH)
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Appeal No. 2001-2168
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